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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,717	07/25/2003	Scott E. Andersen	38-21(15878)D	2211

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EXAMINER	
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ART UNIT	PAPER NUMBER
1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/626,717	ANDERSEN ET AL.	
	Examiner	Art Unit	
	Jehanne S. Sitton	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4 and 6-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4 and 6-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2-2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Currently, claims 1-2, 4, 6-8 and newly added claims 9-13 are pending in the instant application. All the amendments and arguments have been thoroughly reviewed but are deemed insufficient to place this application in condition for allowance. The following rejections are either newly applied, as necessitated by amendment or are reiterated. They constitute the complete set being presently applied to the instant Application. Response to Applicant's arguments follow. This action is FINAL.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. In view of the recent publication of new examples for the Written Description guidelines, the Written Description rejection of claims 1, 4, and 6, made in the previous office action are withdrawn. The rejection is moot with regard to claims 3 and 5 as they are canceled.

Claim Rejections - 35 USC § 101

4. Claims 1-2, 4, and 6-13 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility.

The claims are drawn to a substantially purified nucleic acid molecule comprising SEQ ID NO: 11 (claim 1), which encodes a wheat protein or fragment thereof (claim 2) as well as sequences having between 90%, 95%, 98%, 99% and 100% sequence identity with the entire length of SEQ ID NO: 11 (claims 4, 9-13). The claims are also drawn to a substantially purified nucleic acid molecule comprising (claim 6) or consisting (claim 7) of a fragment of about 50 to

about 100 residues wherein the fragment exhibits complete complementary to a sequence of SEQ ID NO: 11, the complements thereof, as well as such molecules which comprises a region having a single nucleotide polymorphism (claim 8). Claim 13 is also drawn to a substantially purified nucleic acid molecule which hybridizes under stringent conditions to the nucleic acid sequence of SEQ ID NO: 11, or the complement thereof. Claims 1, 2 and 7 do not allow for internal variations within SEQ ID NO: 11. Claims 4, 6, 8, and 9-13 allow for internal variations. Such claims further encompass mutants, variants, and homologs from any plant or any wheat plant (claim 2), of genes, full open reading frames, fusion constructs and cDNAs.

The specification teaches that the claimed nucleic acid is an EST isolated from a wheat cDNA library. The claimed invention is not supported by a specific utility because the disclosed uses of the polynucleotide are not specific and are generally applicable to any EST. The specification discloses many potential uses for the polynucleotide including use as molecular tags to isolate genetic regions, isolate genes, map genes and determine gene function (page 13), to determine if genes are members of a particular gene family, to obtain full length genes (page 14), to isolate promoters and flanking sequences (page 32), for use in marker assisted breeding programs, to hybridize to its complement, to encode proteins, to obtain molecules from other plants (page 30), and to determine whether a plant contains a mutation (page 32). These are non-specific uses that are applicable in general to polynucleotides isolated from wheat and not particular or specific to the polynucleotide claimed.

Further, the claimed polynucleotide is not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. A starting material that can only be used to produce a final product does not have substantial asserted utility in those

instances where the final product is not supported by a specific and substantial utility. For example, the specification teaches that the claimed nucleic acids can be used to identify a polymorphism. However, this is not considered to be a specific and substantial utility. The utility is not specific because it is a property of all wheat plant nucleic acids that they could be used to search for and try to identify a polymorphism. Further, the asserted utility is not substantial because it is a utility that is performed only to accomplish additional research. All discussions regarding polymorphisms in the specification are generic in nature. The specification does not teach any particular polymorphisms in SEQ ID NO: 11. The specification does not disclose an association between any particular polymorphisms and any phenotypic trait. The specification provides no indication as to what the nucleic acids are markers for. Polymorphisms are naturally occurring variations within sequences, which themselves may not have any meaningful use. To determine whether a nucleic acid contains a polymorphism would first require comparing the sequence of SEQ ID NO: 11 to other newly isolated nucleic acids. Then, upon identifying a nucleic acid variation, one would need to determine whether such a variation had any meaningful use – e.g., whether the variation was associated with a particular trait or characteristic of a particular strain of wheat plant. Therefore, the nucleic acids of SEQ ID NO: 11 may only be used to search for polymorphisms and if such polymorphisms are identified then the functional/biological activities of the polymorphisms could potentially be elucidated. Such research projects do not constitute a "real-world" use in currently available form.

As with the use of a nucleic acid to detect polymorphisms, a substantial utility for the nucleic acid can only be elucidated once the function of the nucleic acid or the product encoded by the nucleic acid is determined. The present specification does not teach a specific functional

or biological activity associated with the nucleic acid of SEQ ID NO: 11 or a protein encoded by SEQ ID NO: 11. SEQ ID NO: 11 may be a portion of a full length open reading frame, but the specification does not teach which protein is actually encoded by SEQ ID NO: 11. For example, it is not clear if nucleotide number 1 is the first nucleotide in a codon, or the last. The specification does not teach an association between the claimed nucleic acids and any particular condition in plants. In the absence of such information, the skilled artisan would not know how to interpret the results of methods which determine the expression of an mRNA or protein and would not know how to use a plant that was transformed with the claimed nucleic acids.

Likewise, none of the potential promoters, flanking sequences, mutations, or genes that are to be identified as final products resulting from processes involving the claimed nucleic acid have asserted or identified specific and substantial utilities. The research contemplated by the applicants to characterize potential promoters, flanking sequences, mutations, and genes does not constitute a specific and substantial utility.

Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds. Neither the specification as filed nor any prior art of record discloses or suggests any property or activity for the claimed polynucleotides such that another non-asserted utility would be well established for the compounds.

The instant situation is analogous to that which was addressed in *Brenner v. Manson*, 148 USPQ 689 (1966) and *In re Fisher*, 76 USPQ2d 1225 (CAFC 2005). In *Brenner v. Manson*, the court held that 35 U.S.C. 101 requires that an invention must have either an immediately apparent or fully disclosed "real world" utility. The court held that :

"The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility…[u]nless and until a process is refined and developed to this point where specific benefit exists in currently available form there is insufficient justification for permitting an appellant to engross what may prove to be a broad field…a patent is not a hunting license…[I]t is not a reward for the search, but compensation for its successful conclusion."

In Fisher, the court held that Fisher's asserted uses for ESTs did not qualify as either specific or substantial utilities under *Brenner v. Manson*.

Claim Rejections - 35 USC § 112

5. Claims 1-2, 4, and 6-13 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Response to Arguments

6. The response traverses the rejections under 35 USC 101 and 112/first paragraph enablement for the same reasons. The response asserts that one use of the elected SEQ ID NO: 11 can be shown by a BLASTN analysis, which is a well-known and conventional technique that can be used to obtain information on nucleic acid sequences. This argument has been thoroughly reviewed but was not found persuasive. Although the specification at page 5, explains how a BLASTN search is performed, the specification provides no specific or substantial utility for SEQ ID NO: 11. Any nucleic acid sequence, including any sequence from a wheat plant, can be used in a BLAST analysis. Such use in therefore not specific. This utility is not substantial because no substantial utility is set forth in the specification regarding any particular sequence obtained using BLAST analysis with SEQ ID NO: 11, nor what the specific and substantial utility of that sequence would be. Although the response asserts that SEQ ID NO: 11 has

utilities specific to it and not generally applicable to any nucleic acid in that it can be used to isolate genes, map genes, and determine gene function associated with protein storage, none of these uses are set forth in the specification, nor were they well established at the time the invention was filed. The specification merely discloses that the skilled artisan may perform a BLASTN search on the sequences disclosed to then determine if a specific and substantial utility exist for the sequences in the specification. This is not a specific and substantial utility but rather an invitation for the artisan to then determine whether a specific and substantial utility exists. At pages 45 and 53, the specification is silent with regard to proteins associated with protein storage. They only generally teach how to monitor the expression of proteins in general as well as transformation of plants in general.

The arguments at page 9, that "Applicant's respectfully submit that by showing that the claimed SEQ ID NO: 11 is reasonably correlated with a known protein encoding sequence, the utility of SEQ ID NO: 11 is specific, substantial, and credible" is not found persuasive. The specification is completely silent as to any correlation between SEQ ID NO: 11 and any known protein encoding sequence. The correlation asserted in the response is with regard to an alignment performed after the invention was filed with a protein sequence referenced in a publication after the filing date of the instant invention. None of this information was known to the skilled artisan at the time the invention was filed, either by disclosure in the specification or a well established utility in the prior art. The citation of the website at page 9 of the response is also not persuasive as it does not provide any indication that the specification, at the time of filing provided any guidance as to any of the sequences being homologous to a storage protein. Although the response asserts that storage proteins are important in human nutrition, neither the

specification nor the response disclose how the skilled artisan would use SEQ ID NO: 11 for human nutrition. It is specifically noted that the patent application provides absolutely no disclosure or assertion of a specific, substantial, or credible utility based upon homology to an existing nucleic acid or protein having an accepted utility. The homology analysis relied on by applicants is to a sequence taught in the art after the instant application was filed.

The response's assertion with regard to "reasonable correlation" has been thoroughly reviewed but was not found persuasive. In *Fujikawa v. Wattanasin*, the issue referenced in the response related to reasonable correlation between in vitro and in vivo pharmacological activity of a compound. However, in the instant application, the specification fails to disclose any in vitro or in vivo activity for SEQ ID NO: 11 or a protein, if one exists, encoded by SEQ ID NO: 11.

The arguments made at page 10, that the examiner has provided no support for the assertion that the utilities of SEQ ID NO: 11 are not specific, substantial, or credible are not found persuasive for the reasons made of record in the rejection set forth above and the reasons already made of record.

The response references a search which showed 95% identity over 92% of a clone from a cDNA library and asserts that the sequence was obtained by Kawura et al. Plant Physiol, vol. 139, pages 1870-1880, 2005, and that the utility of SEQ ID NO: 11 is supported by a confirmatory BLAST analysis. It is noted, however, the response does not teach what database this alignment is obtained from, nor which sequence from Kawaura this corresponds to. Further, the specification does not provide any guidance whatsoever as to which portions from within SEQ ID NO: 11 should be searched, leaving it to the artisan to determine for themselves, what

information may be gleaned from the disclosed sequence. Regardless of such, however, it is noted that the instant application effective priority date is 6/15/2000 and the filing date of the instant application is 7/25/2003, while the paper cited was published in 2005. The specification at the time the invention was filed only generally discloses that the SEQ ID NOS can have high homology to wheat proteins but does not teach what these wheat proteins are, how they function, or whether any homology less than 100% identity would provide for a predictable correlation between the structure and function of the putative unknown, undisclosed homologue. However, In *Brenner v. Manson*, the court held that : "...a patent is not a hunting license...[I]t is not a reward for the search, but compensation for its successful conclusion." Here, the specification does not teach homology to storage proteins, nor what the utility of a storage protein is or whether all storage proteins have the same structure and function or whether less than 100% identity to a storage protein would predictably determine what the specific function of that protein was. The reference cited in the response was published after the instant invention was filed and does not provide for a well established utility for SEQ ID NO: 11 at the time of the invention. Accordingly, the response's reference to *In re Fisher*, and *Raytheon Co. v. Roper Corp* are not persuasive to overcome the rejection. If applicants are relying on the fact that BLAST analysis can identify homologues, it is noted that the claims are not directed to methods of BLAST analysis but rather to a nucleic acid molecule for which the specification teaches no specific or substantial utility. The specification provides no teaching of any immediate benefit to the public regarding the sequence of SEQ ID NO: 11. The fact that the citation applicants are relying on is after the filing date of the invention illustrates that no immediate benefit has been

disclosed by the specification at the time the invention was filed nor was it well established in the art at the time the invention was filed

The rejections are therefore maintained.

7. Claims 2 and 8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a substantially purified nucleic acid molecule which comprises SEQ ID NO: 11 and encodes a wheat protein (claim 2), as well as a substantially purified nucleic acid molecule comprising a fragment from about 50 to about 100 nucleotide residues which exhibit complete complementarity to SEQ ID NO: 11 and comprises a region which has a single nucleotide polymorphism (claim 8).

The specification teaches the sequence of SEQ ID NO: 11. SEQ ID NO: 11, per se, meets the written description requirement of 35 USC 112, first paragraph. However, SEQ ID NO: 11 is an EST, and is less than a full length open reading frame. It appears to be a fragment of a larger protein since it was isolated from a Triticum aestivum cDNA library. However, the specification does not teach the function of the larger protein encoded by SEQ ID NO: 11, and provides no description of the remainder of the coding sequence of which SEQ ID NO: 11 appears to be a part of. It is not clear what peptide is encoded by SEQ ID NO: 11, as the specification does not teach, for example, if nucleotide position #1 of SEQ ID NO: 11 is the first

nucleotide in a codon, or the second or third. Accordingly, it is not even clear that SEQ ID NO: 11 encodes a protein (claim 2). Claim 2 specifically recites a nucleic acid which encodes a wheat protein, or fragment of a wheat protein. However, the specification does not teach what structural requirements of the genus of nucleic acids of claim 1 make a sequence a wheat protein vs that of another plant, or organism. It is not clear which structural aspects of SEQ ID NO: 11, distinguish it from "non wheat" proteins. Accordingly, it is not representative of the genus of sequences encompassed by the claims. Further, claim 8 encompass sequences which possess variations with regard to the sequence of SEQ ID NO: 11, such as allelic variants and mutants. As such, each member of the claimed genus does not contain the same structural feature. This large variable genus of nucleic acid molecules is not represented by the single sequence of SEQ ID NO: 11. The specification does not disclose a single variant or homolog of SEQ ID NO: 11, nor any sequence with a "single nucleotide polymorphism". There is no structure function correlation between the single disclosed species, and the large genus of mutants and allelic variants, encompassed by the broadly claimed invention.

Beyond providing the sequence data for SEQ ID NO: 11, the specification provides no teaching or guidance which correlates the sequence of SEQ ID NO: 11 to its function, which amino acids in the protein encoded by SEQ ID NO: 11 are critical to its function, or how to modify SEQ ID NO: 11 to obtain any specific mutant, or variant. It is not clear which positions with SEQ ID NO: 11 can be substituted or altered without resulting in a loss of the function of SEQ ID NO: 11.

While one could argue that the claimed genus of polynucleotides is adequately described since one can identify these polynucleotides by sequence comparison using the

polypeptide/polynucleotide structures disclosed in the instant application or the prior art, the state of the art teaches that sequence comparison alone is not a reliable indicator of a protein's function. For example, Skolnick (Skolnick and Fetrow, TIBTECH, January 2000, vol. 18, pp 34-39) teaches (p. 35, "Box 1") that a common protein characteristic that makes functional analysis based only on homology especially difficult is the tendency of proteins to be multifunctional. Skolnick teaches that for example, lactate dehydrogenase binds NAD, substrate, and zinc and performs a redox reaction and that each of these occurs at different functional sites that are in close proximity and the combination of all four sites creates the fully functional proteins. Skolnick teaches that because the sequence identity between subfamilies is so high, standard sequence similarity methods could easily misclassify new sequences as members of the wrong subfamily if the functional sites are not carefully considered.

The genus of polynucleotides comprised by the claims is a large variable genus, which can potentially encode proteins of diverse functions. The specification only discloses a single species of the genus, i.e. the polynucleotide of SEQ ID NO: 11, which is insufficient to put one of skill in the art in possession of all attributes and features of all species within the genus. The specification fails to teach any other relevant identifying characteristics which would identify a sequence as a variant or mutant (claim 8) or encoding a wheat protein (claim 2). For example, with regard to claim 2, the specification is silent as to which nucleotides are required to encode a wheat protein or fragment of a wheat protein. Thus one skilled in the art cannot reasonably conclude that applicant had possession of the claimed invention at the time the instant application was filed with respect to claims 2 and 8.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116.)

The skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993), and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

Response to arguments

8. The response traverses the rejection. The arguments as they pertain to the rejection of claims 2 and 8 will be addressed. All other arguments are moot in view of the withdrawal of the rejection over claims 1, 4 and 6. The response asserts that an adequate written description of a genus of nucleic acids, such as those recited in claims 1-4, 6 and 8 may be achieved by either "'a recitation of a representative number of [nucleic acid molecules] defined by nucleotide sequence, falling within the scope of genus or of a recitation of structural features common to the members of the genus'... The feature relied upon to describe the claimed genus must be capable of distinguishing members of the claimed genus from non members" (page 15, lat para). The response further asserts that the position made by the Examiner, that it is not clear if SEQ ID NO: 11 encodes a protein "misses the point of the written description rejection ...[because] it is well established law that use of the transitional term "comprising" properly leaves the claims "open for the inclusion of unspecified ingredients in even in major amounts"..." This argument has been thoroughly reviewed but was not found persuasive. With regard to claim 2, the specification does not teach any wheat protein or fragment of a wheat protein encoded by either SEQ ID NO: 11 or a nucleic acid comprising SEQ ID NO: 11. With regard to claim 8, the specification does not teach any nucleic acid sequence within SEQ ID NO: 11 or comprising SEQ ID NO: 11 which contains a single nucleotide polymorphism

Claim 2 is a subgenus of claim 1. While the skilled artisan would be able to distinguish which sequences comprised SEQ ID NO: 11 and which do not, the specification provides absolutely no guidance or description for the skilled artisan to be able to distinguish members of the subgenus of claim 2 from non members. The fact that it is not clear if SEQ ID NO: 11

encodes a protein is particularly relevant to this situation because the fact that a sequence comprises SEQ ID NO: 11 alone, does not distinguish members of the subgenus of claim 2 from non members. The specification does not teach what structural requirements of the genus of nucleic acids of claim 1 encode a wheat protein vs that of another plant, or organism. It is not clear which structural aspects of SEQ ID NO: 11, distinguish it from encoding "non wheat" proteins. Claim 8 is a subgenus of claim 6 and is specifically recited to comprise a region having a single nucleotide polymorphism. A single nucleotide polymorphism (SNP) is a naturally occurring allelic variant. However, the specification does not teach if SEQ ID NO: 11, or a sequence comprising SEQ ID NO: 11 contains a single nucleotide polymorphism. The specification provides no description or guidance for the skilled artisan to be able to distinguish a nucleic acid that contains a SNP from a mutant or variant which is constructed by a researcher, for example. Accordingly, in this situation as well, the specification fails to describe the necessary structural attributes that distinguishes members of the subgenus of claim 8 from non members. In the situation for claims 2 and 8, the sequence of SEQ ID NO: 11, or a fragment from about 50 to about 100 nucleotide residues of SEQ ID NO: 11 are the only common structural features recited for claims 2 and 8 respectively. However, in each situation, this feature does not distinguish members of the claimed genus, from non members. As such, contrary to the arguments set forth in the response, Applicants have not met the burden set forth by the courts in *Eli Lilly and Co*, (Fed Cir 1997). Accordingly, one of skill in the art would recognize that applicants were not in possession of the invention claimed in claims 2 and 8. For these reasons and the reasons made of record above, the rejection is maintained for claims 2 and 8.

Claim Rejections - 35 USC § 102

9. Claim 13 is rejected under 35 U.S.C. 102(a) as being anticipated by EST accession number AW566142 (March 10, 2000).

Accession number AW566142 teaches a nucleic acid molecule which has "a" nucleotide sequence which exhibits 90-100% identity with portions of SEQ ID NO: 11. The alignment between the AW566142 molecule and SEQ ID NO 11 is set forth below. Numerous contiguous regions of 100% identity between the two molecules are illustrated in the alignment.

```
AW566142
LOCUS       AW566142                 562 bp    mRNA    linear   EST 10-MAR-2000
DEFINITION  660062E10.y1 660 - Mixed stages of anther and pollen Zea mays cDNA,
            mRNA sequence.
ACCESSION   AW566142
VERSION     AW566142.1  GI:7227501
KEYWORDS    EST.
SOURCE      Zea mays
  ORGANISM  Zea mays
            Eukaryota; Viridiplantae; Streptophyta; Embryophyta; Tracheophyta;
            Spermatophyta; Magnoliophyta; Liliopsida; Poales; Poaceae; PACCAD
            clade; Panicoideae; Andropogoneae; Zea.
REFERENCE   1  (bases 1 to 562)
  AUTHORS   Walbot,V.
  TITLE     Maize ESTs from various cDNA libraries sequenced at Stanford
            University
  JOURNAL   Unpublished (1999)
COMMENT     Contact: Walbot V
            Department of Biological Sciences
            Stanford University
            855 California Ave, Palo Alto, CA 94304, USA
            Tel: 650 723 2227
            Fax: 650 725 8221
            Email: walbot@stanford.edu
            Plate: 660062  row: E  column: 10.

  Query Match           60.1%;  Score 235.4;  DB 7;  Length 562;
  Best Local Similarity   79.7%;  Pred. No. 2.5e-40;
  Matches  307;  Conservative    0;  Mismatches   66;  Indels   12;  Gaps    2

Qy          8 ACCAAGGTGGCCGCCAAGGTCTTCGAGCTCGACCCGGACGGAATGGTGCAGGCGCTGGCC 67
              | || ||| | ||||| |  |||||||  |||||| |||||| |||||| |||||| ||
Db          7 AGCAGGGTCGTCGCCAGGTCCTTCGAGGCCGACCCCGACGGAGTGGTGCGGGCGCTCGCG 66

Qy         68 GCGGTGCTGCGGGACAAGATCACCATGCCCGGCCAGCTCATGACCGACGGCCGCGACGCC 127
              |||||| |||| | ||||| ||||||||||||||| ||| ||||||| ||||||||||||| |
Db         67 GCCGTCATGCGAGCCAAGGTCACCATGCCCGGCGAGCGCATGACGGACGGCCGCGACGAC 126

Qy        128 GACTTGTTCGAGCACTTCTCGGCGGTCGCGCAGCGCACCGGGGTGTACACGGCAAGAGAC 187
              | | ||||| ||||||||||||| |||||||| |||||||||||||||    |||
Db        127 AGCCTCTTCGACCACTTCTCGGCGGTGGCGCAGCGCGCCGGGGTGTACACGGCGGCGGAC 186

Qy        188 TACGGCGACATGGTGGAGCACTTCGTGCGTAGGTGGAAGGTGGCGGACCTCGGCGGGGGG 247
              ||||||||||||||||||||||||||||| | ||||| ||||||||  |||  ||
Db        187 TACGGCGACATGGTGGAGCACTTCGTGCGCACGTGGAGGGTGGCGGGGCTCCAGGG---- 242
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Qy       248 CAGCTGTCCGGGGAGGGGCGGCCGCGCGCAGGAGTACGTGTGCGGGCTGCCGCGCAAGATC 307
             |||||| || |||||||| |||||||| || ||||||||||||||||||||||||||||||
Db       243 --GCTGTCTGGCGAGGGGCGCCGCGCGCAAGACTACGTGTGCGGGCTGCCGCGCAAGATC 300

Qy       308 CGGCGGGTGGAGGAGCTGGCCCACGACGCGCTGATCAAAGCCGCAAAAGAGCCCGAGTTC 367
             ||  || ||||||||||||||||||||| |         ||| ||||||| || | |
Db       301 CGCAGGATGGAGGAGCTGGCCCACGACCGTG------CCGCCCAAAAAGAGGCCCAATCT 354

Qy       368 GCAAGGTTCAGCTGGGTCTTCGACA 392
             | ||  |||||||||| |||||||
Db       355 GTCAGCATCAGCTGGGTGTTCGACA 379
```

Additionally, claim 13 does not set forth any particular hybridization conditions. It is a property of the nucleic acid of Accession number AW566142 to hybridize at the broad conditions encompassed by the claims. For example, nucleotides 67-126 have a calculated Tm of 83 degC and a salt adjusted Tm of 78 degC (on the world wide web at promega.com/biomath/calc11.htm). The sequence would therefore hybridize at the broad conditions set forth in the claims.

10. Claim 13 rejected under 35 U.S.C. 102(a) as being anticipated by EST accession number AI677542 (Feb 2000, first made available to NCBI May 25, 1999).

Accession number AI677542 teaches a nucleic acid molecule which has "a" nucleotide sequence which exhibits 90-100% identity with portions of SEQ ID NO: 11. The alignment between the AI677542 molecule and SEQ ID NO 11 is set forth below. Numerous contiguous regions of 100% identity between the two molecules are illustrated in the alignment.

```
LOCUS       AI677542                552 bp    mRNA    linear   EST 02-FEB-2000
DEFINITION  605056G04.xl 605 - Endosperm cDNA library from Schmidt lab Zea mays
            cDNA, mRNA sequence.
ACCESSION   AI677542
VERSION     AI677542.1  GI:4887443
KEYWORDS    EST.
SOURCE      Zea mays
  ORGANISM  Zea mays
            Eukaryota; Viridiplantae; Streptophyta; Embryophyta; Tracheophyta;
            Spermatophyta; Magnoliophyta; Liliopsida; Poales; Poaceae; PACCAD
            clade; Panicoideae; Andropogoneae; Zea.
REFERENCE   1  (bases 1 to 552)
  AUTHORS   Walbot,V.
  TITLE     Maize ESTs from various cDNA libraries sequenced at Stanford
```

```
            University
  JOURNAL   Unpublished (1999)
COMMENT     Contact: Walbot V
            Department of Biological Sciences
            Stanford University
            855 California Ave, Palo Alto, CA 94304, USA
            Tel: 650 723 2227
            Fax: 650 725 8221
            Email: walbot@stanford.edu
            Plate: 605056  row: G  column: 04.
FEATURES             Location/Qualifiers
     source          1..552
                     /organism="Zea mays"
                     /mol_type="mRNA"
                     /cultivar="Ohio43"
                     /db_xref="taxon:4577"
                     /tissue_type="nucellar, embryo, and endosperm"
                     /dev_stage="10-14 days post-pollination"
                     /lab_host="DH5(alpha)"
                     /clone_lib="605 - Endosperm cDNA library from Schmidt lab"
                     /note="Organ: Kernel; Vector: pAD-GAL4-2'; Site_1: EcoRI;
                     Site_2: XhoI; Kernel endosperm cDNA library from Schmidt
                     lab"

  Query Match             38.9%;  Score 152.4;  DB 1;  Length 552;
  Best Local Similarity   65.6%;  Pred. No. 1.6e-22;
  Matches  257;  Conservative    0;  Mismatches  126;  Indels    9;  Gaps    2;

Qy          1 GGCCTACACCAAGGTGGCCGCCAAGGTCTTCGAGCTCGACCCGGACGGAATGGTGCAGGC 60
              ||| |||      | |  |   || |  |  |||| ||||||||||||    ||||  ||
Db        480 GGCGTACGGGCGCATCGTGGAGCAGCTGCTGCAGCTGGACCCGGACGGCGCCGTGCTCGC 421

Qy         61 GCTGGCCGCGGTGCTGCGGGGACAAGATCACCATGCCCGGCCAGCTCATGACCGACGGCCG 120
              | ||| |  || ||||  |  |||||||||||||  || |||||  |||||||||
Db        420 CGTCGCGGACATGATGCGCAAGCGGATCACCATGCCCGCGCACCTCATGCACGACGGCCG 361

Qy        121 CGACGCCGACTTGTTCGAGCACTTCTCGGCGGTCGCGCAGCGCACCGGGGGTGTACACGGC 180
              ||||   ||| ||||||||||||| | || ||||| ||||||  ||| |||||||| ||
Db        360 CGACATGGACCTGTTCGAGCACTTCGCCGCCGTCGCCCAGCGCCTCGGCGTGTACACCGC 301

Qy        181 AAGAGACTACGGCGACATGGTGGAGCACTTCGTGCGTAGGTGGAAGGTGGCGGACCTCGG 240
              | |||||||  ||||| || |||  | | ||     ||||||||| ||| |   || |
Db        300 CCGGGACTACGCGGACATCGTCGAGTTCCTTGTCAAGCGGTGGAAGCTGGAGACACTGGA 241

Qy        241 CGGGGGGCAGCTGTCCGGGGAGGGGCGGCGCGCAGGAGTACGTGTGCGGGCTGCCGCG 300
              | ||    ||| ||||| ||||| ||  | ||   ||| | ||| ||||||||  |||
Db        240 GAGCGG---GCTCTCCGGCGAGGGCCGCAGGGCCAGGGACTTCGTCTGCGGGCTCGCGCC 184

Qy        301 CAAGATCCGGCGGGTGGAGGAGCTGGCCCACGACCGCGTGATCAAAGCCGCAAAAGAGCC 360
              | ||| || ||||  | |||||  ||| | ||| | |  |  || |      | |||||
Db        183 GAGGATGCGCCGGGCCGCGGAGCGCGCCGAGGACAGGGCCAAGAAGG------ACGAGCC 130

Qy        361 CGAGTTCGCAAGGTTCAGCTGGGTCTTCGACA 392
              |  | | |  | ||||||||| |||| || |
Db        129 CAGGATGGTCAAGTTCAGCTGGATCTTTGATA 98
```

Additionally, claim 13 does not set forth any particular hybridization conditions. It is a property of the nucleic acid of Accession number AI677542 to hybridize at the broad conditions encompassed by the claims. For example, nucleotides 301-360 have a calculated Tm of 82 degC

and a salt adjusted Tm of 77 degC (on the world wide web at promega.com/biomath/calc11.htm). The sequence would therefore hybridize at the broad conditions set forth in the claims.

11. Claim 13 is rejected under 35 U.S.C. 102(e) as being anticipated by Cahoon (Cahoon et al; US Patent 6,762,345).

Cahoon teaches a nucleic acid molecule which has "a" nucleotide sequence which exhibits 90-100% identity with portions of SEQ ID NO: 11. The alignment between SEQ ID NO 13 taught by Cahoon and SEQ ID NO 11 is set forth below. Numerous contiguous regions of 100% identity between the two molecules are illustrated in the alignment.

```
LOCUS       AR569415                1623 bp    DNA     linear   PAT 14-DEC-2004
DEFINITION  Sequence 13 from patent US 6762345.
ACCESSION   AR569415
VERSION     AR569415.1  GI:56569940
KEYWORDS    .
SOURCE      Unknown.
  ORGANISM  Unknown.
            Unclassified.
REFERENCE   1  (bases 1 to 1623)
  AUTHORS   Cahoon,R.E., Famodu,O.O. and Shen,J.B.J.
  TITLE     Plant stearoyl desaturases
  JOURNAL   Patent: US 6762345-A 13 13-JUL-2004;
            E. I. du Pont de Nemours and Company; Wilmington, DE
FEATURES             Location/Qualifiers
     source          1. .1623
                     /organism="unknown"
                     /mol_type="genomic DNA"


  Query Match             39.2%;  Score 153.8;  DB 2;  Length 1623;
  Best Local Similarity   67.4%;  Pred. No. 9.4e-26;
  Matches  234;  Conservative    0;  Mismatches  107;  Indels    6;  Gaps    1;

Qy          2 GCCTACACCAAGGTGGCCGCCAAGGTCTTCGAGCTCGACCCGGACGGAATGGTGCAGGCG 61
              |||||||||||| | | ||  ||| |||||||| | ||||| ||    |  ||||  |||
Db        889 GCCTACACCAAGATAGTCGAGAAGCTCTTCGAGATGGACCCTGATTACACAGTGCTTGCG 948

Qy         62 CTGGCCGCGGTGCTGCGGGACAAGATCACCATGCCCGGCCAGCTCATGACCGACGGCCGC 121
                | ||| |   || || || | |||||||| ||||| | ||| ||||||  ||||||
Db        949 TTTGCTGACATGATGAGGAAGAATCACGATGCCAGCCCATCTCATGTACGACGGTAAG 1008

Qy        122 GACGCCGACTTGTTCGAGCACTTCTCGGCGGTCGCGCAGCGCACCGGGGTGTACACGGCA 181
              |||| | || ||||||||||||||   ||||| |||||| |    || || ||||| ||
Db       1009 GACGACAACCTGTTCGAGCACTTCAGCGCGGTGGCGCAGAGGCTGGGCGTCTACACCGCC 1068

Qy        182 AGAGACTACGGCGACATGGTGGAGCACTTCGTGCGTAGGTGGAAGGTGGCGGACCTCGGC 241
              | |||||||| ||||||  | |||  | | || |  |||||||| || ||||| |||
Db       1069 AAAGACTACGCCGACATCCTCGAGTTCCTGGTCCAGAGGTGGAAAGTCGCGGAGCTCACA 1128

Qy        242 GGGGGGCAGCTGTCCGGGGAGGGGCGGCGCGCGCAGGAGTACGTGTGCGGGCTGCCGCGC 301
```

```
                ||      |||||| || || ||| |  ||||||||||| |  || ||      || |||
Db       1129 GG------GCTGTCTGGAGAAGGGAGAAGCGCGCAGGACTTTGTCTGTACCTTGGCGCCG 1182

Qy        302 AAGATCCCGCGCGGTGGAGGAGCTGGCCCACGACCGCGTGATCAAAGC 348
              | |||| |||||| |||| ||    || || |  | | ||  ||||
Db       1183 AGGATCAGGCGGCTGGATGATAGAGCTCAAGCGAGGGCGAAGCAAGC 1229
```

Additionally, claim 13 does not set forth any particular hybridization conditions. It is a property of the nucleic acid of Cahoon to hybridize at the broad conditions encompassed by the claims. For example, nucleotides 889-948 have a calculated Tm of 75 degC and a salt adjusted Tm of 70 degC (on the world wide web at promega.com/biomath/calc11.htm). The sequence would therefore hybridize at the broad conditions set forth in the claims.

12. Claim 13 is rejected under 35 U.S.C. 102(b) as being anticipated by Genbank Accession number AF020203 (1998).

Accession number AF020203 teaches a nucleic acid molecule which has "a" nucleotide sequence which exhibits 90-100% identity with portions of SEQ ID NO: 11. The alignment between the AF020203 molecule and SEQ ID NO 11 is set forth below. Numerous contiguous regions of 100% identity between the two molecules are illustrated in the alignment.

```
AF020203
LOCUS       AF020203               1001 bp    mRNA    linear   PLN 15-MAY-1998
DEFINITION  Pelargonium x hortorum stearoyl-ACP desaturase (pxh-A) mRNA,
            partial cds.
ACCESSION   AF020203
VERSION     AF020203.1  GI:3133286
KEYWORDS    .
SOURCE      Pelargonium x hortorum
  ORGANISM  Pelargonium x hortorum
            Eukaryota; Viridiplantae; Streptophyta; Embryophyta; Tracheophyta;
            Spermatophyta; Magnoliophyta; eudicotyledons; core eudicotyledons;
            rosids; Geraniales; Geraniaceae; Pelargonium.
REFERENCE   1  (bases 1 to 1001)
  AUTHORS   Schultz,D.J., Mumma,R.O., Cox-Foster,D., Craig,R. and Medford,J.I.
  TITLE     Geranium stearoyl-ACP desaturase
  JOURNAL   Unpublished
REFERENCE   2  (bases 1 to 1001)
  AUTHORS   Schultz,D.J., Mumma,R.O., Cox-Foster,D., Craig,R. and Medford,J.I.
  TITLE     Direct Submission
  JOURNAL   Submitted (19-AUG-1997) Botany, MSU, 166 Plant Biology Building,
            East Lansing, MI 48824, USA
FEATURES             Location/Qualifiers
```

```
     source          1. .1001
                     /organism="Pelargonium x hortorum"
                     /mol_type="mRNA"
                     /db_xref="taxon:4031"
                     /tissue_type="glandular trichomes"
     gene            <1. .1001
                     /gene="pxh-A"
     CDS             <1. .670
                     /gene="pxh-A"
                     /codon_start=2
                     /product="stearoyl-ACP desaturase"
                     /protein_id="AAC16442.1"
                     /db_xref="GI:3133287"
                     /translation="AEENRHGDLLNKYLYLSGRIDMRQIEKTIQYLIGSGMDPKTENN
                     PYLGFIYTSFQERATFVSHGNTARHAKDHGDLKLAQICGTIAADEKRHETAYTKIVEK
                     LFELDPDGTVMALSDMMRKKISMPAHLMFDGKDDNLFEHFSRSQRLGVYTARDYADIL
                     EFLVARWNVDKLTGLSGEGRRAQDYVCGLAQRIRRLEERAQKRAKEATMVPFSWIFGR
                     EVLL"

  Query Match             38.0%;  Score 148.8;  DB 4;  Length 1001;
  Best Local Similarity   65.7%;  Pred. No. 1.5e-24;
  Matches  251;  Conservative    0;  Mismatches  122;  Indels    9;  Gaps    2;


Qy          2 GCCTACACCAAGGTGGCCGCCAAGGTCTTCGAGCTCGACCCGGACGGAATGGTGCAGGCG 61
              ||||||||||| | |  | ||| |||||||||||||||| ||||| |  ||    ||||
Db        284 GCCTACACCAAGATCGTGGAGAAGCTCTTCGAGCTCGACCCGACGGCACCGTCATGGCG 343

Qy         62 CTGGCCGCGGTGCTGCGGGACAAGATCACCATGCCCGGCCAGCTCATGACCGACGGCCGC 121
              ||  |||   || || || | || |||| | |||| |  || || |||   ||||||
Db        344 CTCTCCGACATGATGAGGAAGAAAATCTCAATGCCGGCACACCTGATGTTTGACGGCAAG 403

Qy        122 GACGCCGACTTGTTCGAGCACTTCTCGGCGGTCGCGGCAGCGCACCGGGGTGTACACGGCA 181
              |||| | || | |||||||| |||||| |  |  | || ||   ||| || ||||| ||
Db        404 GACGACAACCTTTTCGAGCATTTCTCGCGG---TCCCAACGGCTCGGAGTCTACACCGCG 460

Qy        182 AGAGACTACGGCGACATGGTGGAGCACTTCGTGCGTAGGTCGAAGGTGGCGGACCTCGGC 241
              || ||||||| ||||||  |||||  ||| ||   ||| |||| ||||   | |||
Db        461 AGGGACTACGCCGACATATTGGAGTTCTTGGTCGCTAGATGGAACGTGGACAAGCTCAGG 520

Qy        242 GGGGGGCAGCTGTCCGGGGAGGGGCGGCGGCGCAGGAGTACGTGTGCGGCTGCCGCGC 301
              |  |  || |||||||| |||||  | |||| || || |||||||| || |||
Db        521 GG------TCTCTCCGGGGAAGGGCGTAGAGCGCAAGATTATGTGTGCGGGTTGGCGCAG 574

Qy        302 AAGATCCGGCGGGTGGAGGAGCTGGCCCACGACCGCGTGATCAAAGCCGCAAAAGAGCCC 361
              | ||||||| || |||||||||  || ||  |  | | | ||   ||||  | |  |  ||
Db        575 AGGATCCGGAGGTTGGAGGAGCGAGCTCAGAAAAGAGCGAAGGAAGCAACGATGGTTCCT 634

Qy        362 GAGTTCGCAAGGTTCAGCTGGG 383
                 |  ||| |  |||
Db        635 TTCAGCTGGATCTTCGGGAGGG 656
```

Additionally, claim 13 does not set forth any particular hybridization conditions. It is a property of the nucleic acid of Accession number AF020203 to hybridize at the broad conditions encompassed by the claims. For example, the first row of nucleotides (284-343) have a calculated Tm of 80 degC and a salt adjusted Tm of 75 degC (on the world wide web at

promega.com/biomath/calc11.htm). The sequence would therefore hybridize at the broad conditions set forth in the claims.

13. Claim 13 is rejected under 35 U.S.C. 102(b) as being anticipated by NEB catalog (1998/1999), pp. 121, 284.

The specification defines a "substantially purified nucleic acid molecule" as a molecule separated from substantially all other molecules normally associated with it in its native state (page 15). Additionally, the specification teaches that nucleic acid molecules of the invention include the EST nucleic acid molecule of SEQ ID NO: 11 as well as fragments thereof. The specification teaches (page 14) that a fragment may comprise smaller oligonucleotides from about 15 to about 250 nucleotide residues and more preferably about 15 to about 30 nucleotide residues. The term "about" has not been defined. The recitation of "a nucleotide sequence" in claim 13 encompasses sequences from within the recited SEQ ID NO: 11, including oligonucleotides as defined by the specification. The article "a", as defined by the art (see http://www.onelook.com/?w=a&ls=a) referred to as "the indefinite article, signifying one or any". This is contrasted to the word "the" which is defined by the Oxford English dictionary as the definite article, used to refer to a person place or thing that is unique (see http://www.askoxford.com/concise_oed/the?view=uk).

The NEB catalog offered for sale a random primer mix of 12mer and 24mer nucleotide primers. As the calculation below shows, about 3.2×10^8 molecules of every 12-mer and about 9 molecules of every single 24 mer are present in each tube of the 12 and 24 nucleotide mixtures respectively.

a. Molecular weight of 12-mer:

12 x 325 daltons/nucleotide = 3,900 daltons = 3,900 g/mol

b. Total number of possible 12-mers:

$4^{12} = 1.6 \times 10^{7}$ molecules

c. How many molecules of 12-mer in a vial sold by NEB:

1 A260 unit = 33 mg = 3.3×10^{-5} g

3.3×10^{-5} g □ 3,900 g/mol = 8.4×10^{-9} mol

(8.4×10^{-9} mol) x (6.02×10^{23} molecules/mol) = 5×10^{15} molecules

d. How many molecules of each 12-mer in a single vial:

5×10^{15} molecules □ 1.6×10^{7} molecules = 3.2×10^{8} molecules of each 12-mer per vial

e. Molecular weight of 24-mer:

24 x 325 daltons/nucleotide = 7,800 daltons = 7,800 g/mol

f. Total number of possible 24-mers:

$4^{24} = 2.8 \times 10^{14}$ molecules

g. How many molecules of 24-mer in a vial sold by NEB:

1 A260 unit = 33 mg = 3.3×10^{-5} g

3.3×10^{-5} g □ 7,800 g/mol = 4.2×10^{-9} mol

(4.2×10^{-9} mol) x (6.02×10^{23} molecules/mol) = 2.5×10^{15} molecules

h. How many molecules of each 24-mer in a single vial:

2.5×10^{15} molecules □ 2.8×10^{14} molecules = 9 molecules/vial

The claims encompass a very large genus of possible nucleic acids with no particular base composition or length. The NEB catalog vials will inherently and necessarily contain 12 and 24 nucleotides probes encompassed by the claimed recitation. As the specification has not defined the term "about", the claims have been given their broadest reasonable interpretation consistent with the teachings of the specification and the art. Claim 13 is not limited to sequences which are identical to SEQ ID NO: 11 or its' complement.

Additionally, claim 13 does not set forth any particular hybridization conditions. It is a property of the probes taught by NEB to hybridize at the broad conditions encompassed by the claims. For example, the first 12 nucleotides of SEQ ID NO: 11 have a calculated Tm of 38 degC and a salt adjusted Tm of 28 degC. The first 24 nucleotides have a calculated Tm of 64 deg C and a salt adjusted Tm of 59 deg C (on the world wide web at promega.com/biomath/calc11.htm). Probes to these sequences would hybridize at the broad conditions set forth in the claims.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. No claims are allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Sitton whose telephone number is (571) 272-0752. The examiner can normally be reached Monday, Wednesday and Thursday from 9:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Jehanne Sitton/
Primary Examiner
Art Unit 1634